PURPOSE. The objective of this study is to demonstrate the feasibility and effectiveness of the Virtual Assisted Living Umbrella for the Elderly (VALUE) program. VALUE uses videoconferencing, Internet access and physiological/symptom monitoring to provide an assisted living (AL) alternative resources for individuals remaining in their own homes. AL facilities are a growing addition in the elder's continuum of care. The National Center for Assisted Living (NCAL) estimates that there are currently 800,000 clients living in 33,000 licensed AL residences. ¹ The growing acceptance of the aging-in-place philosophy, an aging but increasingly independent population, financial constraints, and increasing shortages of professional health care workers are all converging to limit access to these services. Access becomes an even greater problem for frail elders with limited financial resources, particularly in the urban core and rural areas. With the exception of a few recent studies, AL has not been the focus or beneficiary of telecommunications and information system enhancements that have targeted other points along this care continuum. The VALUE program will combine these technologies into an interactive package placed in each participant's home which will connect participants to assisted living resources, caregivers, family members and neighborhood friends. The anticipated outcome of VALUE will be improvements in health and functional status, self-care behaviors, satisfaction with independent living, utilization of AL-type services, and ability to remain in an independent living circumstance, at similar or less cost than an equivalent resident in an assisted living facility.

The projected increased need for AL services is both a local and national phenomenon. The average age of AL residents is 80 yrs (range of 66-94 yrs); 2/3 are female. They typically suffer from one or more chronic disease, such as heart failure, hypertension, chronic obstructive pulmonary disease, diabetes, and depression. According to the NCAL, more than 50% of AL residents require help with Instrumental Activities of Daily Living (e.g. shopping, preparing meals, housework). The VALUE partner agencies have made similar observations among AL residents and independent living community members who utilize their congregate dining and transportation services (potential VALUE candidates). Monthly rentals for AL residents are typically \$2,000-\$4,000, depending on the level of services provided. These costs would be prohibitive for most elderly residents in our study areas, where almost 60% receive assistance from state and county sources. Thus there is a need for a cost-effective AL alternative that makes it possible for frail elderly to remain living independently in their own home as long as possible. This would reduce the number of new AL residence facilities needed, would contain costs for low and moderate retirement income individuals, and would move toward balancing the increased need versus the decreased availability of professionally trained health care workers. VALUE could shift the AL emphasis from a brick and mortar approach to a technology driven solution. VALUE will offer an effective alternative to traditional AL service providers. This alternative should be attractive to both providers and clients in helping them attain their own goals.

VALUE will be implemented in Minneapolis and Wadena MN. The Minneapolis area has high levels of poverty and large populations of persons over age 60. Wadena County, one of the poorest rural counties in Minnesota, also has a predominantly aging population. There are limited AL facilities for frail elderly, low-income clients in these areas. While telemedicine has traditionally been thought of as a technology for rural sites to overcome significant travel distances, transportation issues are also prevalent in the metro area for both health professionals

providing home services and elderly clients who can no longer drive. Elderly clients living independently in both rural and urban locations find it increasingly more difficult to navigate through automated telephone systems often used for appointments and scheduling of transit, nutrition, and house chores. The Internet access provided by VALUE will make these into essentially one-stop shopping procedures where the user will simply click on needed services, desired times, specific needs (e.g. special care van, car service) and then await an email response confirming the requested service, timing, location and cost. VALUE services will have a significant impact on the viability of community based home-healthcare programs. The nursing shortage is a major issue for our urban core and poor rural communities and shortages are even more pronounced in home-healthcare programs that primarily serve Medicare or Medicaid persons. Developing new approaches to delivering these services is imperative to continuing these programs.

INNOVATION. Traditional AL is defined as housing for the elderly with supportive services in a homelike environment. ² AL residents can determine the services they will utilize, and when and how they will be accessed. The early experiments in developing AL facilities focused on elderly residents who were living in nursing homes because they needed supportive services not otherwise available, but did not need the skilled nursing care. ³ The premise of AL is that providing a combination of housing, healthcare services, and supportive assistance will let residents maintain a higher level of independence and dignity often not possible in traditional nursing homes. ⁴ The VALUE program innovates by extending this concept through technology to networks of frail elders living independently in their own homes. VALUE will use broadband telecommunications to deliver the equivalent of AL healthcare, educational, and supportive services to the client in their home. VALUE will promote timely, socially relevant and clinically meaningful interactions and information exchanges among clients, nurses, and social service providers. AL-type services such as home meal delivery/menu selection, scheduled transportation, medication compliance, handling financial concerns and legal questions, monitoring health conditions, and social interactions will be part of the VALUE program. Video interactions and electronic communication with distant family and neighborhood friends will be another innovative VALUE application. Several recent telemedicine studies have demonstrated that Internet access to health services and information is a viable option across a broad range of populations. Age, education or economic status were not barriers to use. TOP grantee Crozer-Keystone Health System's SeniorSupport On-line network reported subject acceptance and satisfaction with on-line delivery of services, the elderly's ability to adapt to computer-based technology, and an enhanced sense of independence. ⁵ The Every Block a Village program, also a TOP grantee, had the same findings using a similar approach. ⁶ These results are consistent with our TOP TeleHomeCare program for patients receiving skilled home health nursing services, which has also demonstrated improvement in discharge to higher levels of care for the experimental telemedicine group. ^{7,8} Unlike TeleHomeCare and the proposed VALUE program, these other programs did not include any group comparisons to prove that the new technology was better than, or at least as good as, conventional methodologies. Another new study also uses POTS (plain old telephone service) videoconferencing, limited monitoring, and Internet access to educational material for older diabetics needing specialized diabetes related services. ^{9,10} Results for this study are not yet available.

Finally, making VALUE a real, working, beneficial experience requires a unique partnership of community constituencies. It will include clinical partners representing both hospital and social service agency based AL providers in urban and rural Minnesota, county offices, medical device manufacturers, and the major research university within the region. Their ideas and resources will be focused within VALUE to address the needs for a community-based approach to extend the assisted living "aging-in-place" concept. Such a diverse, yet focused group of supporters, will increase the likelihood of VALUE-like programs penetrating the healthcare marketplace once its benefits are demonstrated.

COMMUNITY INVOLVEMENT. In response to the MN Department of Human Services"2030 Report" our state has developed a plan to prepare for the doubling of the population age 65 and older between 2000 and 2030. 11 Its proposed transition to a long-term care system relies on more community-based services in an attempt to reduce cost while providing adequate health care. In 2001, the City of Minneapolis conducted surveys and held community forums to give seniors a voice on the services that are important to them. ¹² Seventyfive percent stated that the most important issue affecting seniors is living independently, and 28% feel that health needs and housing costs are the top two circumstances threatening their living situation. AARP's "Minnesota Long-term CareSurvey" found that 85% of respondents considered remaining in their own homes as long as possible to be very important (see Appendix). These broad state and city studies indicate the need for the VALUE approach to a widely recognized concern. VALUE partners in Wadena have had ongoing discussions about the growing needs for AL services in their region and the potential of a VALUE type program. The Volunteers of America/Minnesota (VOA) recently contacted Dr. Finkelstein to discuss using telemedicine to provide AL services to their mostly poor, elderly clients. VALUE is a direct response to these needs. Our partners have also met with potential VALUE clients in informal senior discussion groups. Feedback has been enthusiastic and supportive, and was similar to responses our research group found when preparing for the TeleHomeCare program. Our partner agencies, representing some of the poorest neighborhoods within the Minneapolis urban area and the poorest rural counties within Minnesota, have recognized that telemedicine and the Internet can provide a cost-effective solution for the delivery of AL type services directly to clients in their homes.

We plan to continually involve the entire user community, as described in the feasibility section. Providers and patients will be involved in the initial planning and pilot testing phases and will continue to provide input during implementation and evaluation via regular teleconferences to review problems and develop solutions, and during both virtual and real visits to client homes. Plans to train end-users (both service providers and VALUE subjects) are based on our experiences with TeleHomeCare. Staff will prepare paper and web-based descriptions of the VALUE process, continually update "frequently asked questions", and instructional sheets for all monitoring and videoconferencing equipment. Problems will also be discussed during weekly staff videoconferences attended by agency and University VALUE personnel. VALUE clients will be trained by VALUE nurses during successive home visits, starting with directions for videoconference use, and followed by separate sessions for Internet access training and use of the specific monitoring devices for each client. Both paper and web-based reminder sheets will be left with the clients for use when needed. This iterative approach was developed and used successfully in our TeleHomeCare program, demonstrating its effectiveness with an older, frail

population. Information technology specialists at each site are part of the VALUE team. They will provide the local, on-going technical expertise for the VALUE program. University staff will be available by telephone and email to consult on new or more intractable problems. A scenario describing **end-user interaction** with the VALUE program is included in the Appendix—"One day in the life of a VALUE client"

Partners. The partner agencies are components of either a rural community hospital organization (Tri-County Hospital) or a large urban senior services organization (Volunteers of America of Minnesota) working primarily with county referred, medical assistance clients. These clinical partners provide the widest possible base of health and social service professionals and client representation. In this capacity, they are the hub of care delivery and health education to their entire community and thus a successful implementation of the VALUE program will immediately make it available to the community at large and not remain restricted to a small group of users. We will conduct weekly videoconferences with clinical partners to provide immediate feedback and problem resolution and to maintain the partner relationship. Finally, our industry partners represent a broad range of medical device expertise and market penetration with large regional and national customer networks. These partners, Nonin Inc and QRS Diagnostics, are developers and manufacturers of medical monitoring devices adaptable for home use. Representatives of industry and healthcare partners will serve on a VALUE advisory board to maintain contact throughout the project period. Descriptive material from our partners is included in the Appendix.

EVALUATION and DISSEMINATION. VALUE creates an independent living situation for elder clients that is designed to be equivalent in many respects to communal AL facilities. The VALUE study is a randomized trial comparing a group receiving the VALUE intervention and a control group following their usual practice. We anticipate that the intervention group will have improved health, functional status, self-care behaviors, satisfaction with their living conditions, utilization of services, and ability to remain living independently at similar or lower cost than the control group. Our evaluation will compare the VALUE intervention and control groups within each geographic area in regard to these outcome measures. All data collection questionnaires described in the implementation section have been validated, tested, and used for similar applications.

The SF-36, ADL/IADL ratings, and perception and client satisfaction scores will be determined at baseline and follow-up for health and well-being, functionality, and subject satisfaction, respectively. ¹³⁻¹⁵ T-tests will compare health status changes between the VALUE intervention and control groups. Health service utilization will be tracked. Fixed and variable provider and client cost data will be collected for both groups. Descriptive statistics will summarize system usage, telemedicine perceptions, and functionality.

While the execution of the evaluation design will be the responsibility of the project staff, an external evaluation specialist, Dr. S. Potthoff, has been included to review and modify the evaluation plan prior to its execution and to review, modify and approve the final report of the project evaluation. She will work with the project team throughout the project to assure that appropriate data is collected, and she will be responsible for directing analysis and interpretation of evaluation data.

Dissemination. A variety of means will be employed to disseminate project results, including presentation at professional meetings (eg. Am Telemed Assoc, Natl Assoc Home Care, Am Soc Aging) and submission of manuscripts for publication in telemedicine, nursing and home care/assisted living journals. The University will disseminate project results to state and national media. Our website will make our project and its results immediately available to the Internet public. Stories will be sent to our partner agency internal newsletters for distribution to their various constituencies, which often are national in scope (e.g. the VOA-MN is a part of the national VOA organization). A letter of support from the AARP-MN affiliate shows the interest of AARP to help in "getting the word out" regarding the success of VALUE. This will provide an important national media outlet for VALUE information. Plans for VALUE will closely follow the successful dissemination effort for our TeleHomeCare project which (to date) includes 14 papers and 18 abstracts in scientific publications, 32 presentations at national, state, and community meetings, articles in local newspapers and institutional newsletters, booths at numerous community health fairs (including Minnesota State Fair, 1.4 million visitors), an Iowa Public Television broadcast, and local radio. The clinical, functional, social, and cost benefits anticipated from VALUE should make it an attractive program for providers to replicate within their specific client base.

PROJECT FEASIBILITY. Technical Approach. **Telecommunications**. The VALUE project uses a network-connected workstation that incorporates a PC platform with a high-speed broadband connection, a large format monitor, a keyboard and mouse, CD ROM, 20GB disk, PC Card adapter, speakers and a ViaVideo digital video camera. ViaVideo is a Polycom product for IP (Internet) videoconferencing that contains both a camera and codec that connects via a USB port. Software will consist of Windows XP, Internet Explorer, the Pocket Medic spirometer software, the ViaVideo software, and custom software for acquiring information from other monitoring devices such as scales and glucometers. This workstation will be installed in each VALUE intervention subject home. PCs with access to the project database will be installed at partner offices in Minneapolis and Wadena.

In previous work we have used POTS based VC, but its low frame rate had both video and audio quality problems. It worked reasonably well for "talking heads" but did not work well for observing the patient engaging in self-care tasks such as taking a blood pressure, demonstrating a range of motion of a limb, or reading the output of a monitoring device held up to the camera. We also found that the utility of Internet access was limited due to both the download speed of the system and the limitations of the browser built into the VC unit. This severely limited the websites that could be accessed. Broadband access will solve this problem. We propose to use broadband connectivity with a minimum of 256KBs. This higher speed access should significantly improve the VC quality. Such access, via DSL, is available in our Minneapolis urban client area and almost all clients in the Wadena base area have DSL access. While broadband access is not universally available in the United States, it is penetrating most areas, as indicated by access in Wadena County, one of the poorer counties in Minnesota.

The VALUE intervention group will access AL type supportive services through a web portal customized for their specific client condition and needed agency services. Clients will choose service options, transmit their choices to the service provider, and await an electronic message

either asking for additional information or confirming the client's request. These interfaces will be developed in consultation with the supportive service providers at each agency, in response to suggestions obtained from client focus groups organized in both the Minneapolis and Wadena client areas. Focus groups will be run by experienced facilitators, following procedures our group developed in the TOP TeleHomeCare project. Family members can purchase compatible equipment to enable them to videoconference with their elderly relatives living at a distance in a VALUE home.

Technical Approach. Home monitoring. VALUE participants will use VC and physiological home monitoring (HM) devices to provide the health monitoring that residents in traditional AL facilities access by visiting their wellness center. Chronically ill subjects will have disease appropriate HM devices for daily use; those with specific acute health problems will receive HM equipment when needed. All VALUE intervention subjects will be trained in the use of the HM devices during VALUE nurse visits. Examples of HM devices are spirometry for determining lung function, pulse oximeters for monitoring blood oxygen levels, scales, blood pressure cuffs, and glucometers. Many clients already own scales and in the case of diabetics, glucometers. Other appropriate HM devices will be provided as needed. Measurements from these devices will be stored directly in VALUE computers, or entered by subjects using customized web forms, or shown to the nurse during virtual visits. The TeleHomeCare project has shown that elderly patients with no prior technical or computer experience can use this type of HM equipment after brief training sessions. Subjects will periodically complete a problem-specific symptom questionnaire on their personal website following a schedule consistent with AL guidelines. They will also periodically complete a brief questionnaire about their ability to perform functions of daily living. Subject data will be downloaded at weekly intervals to the project database.

Applicant Qualifications. The principal investigator, Dr. S. Finkelstein, has been a leader in physiological home monitoring and telemedicine for the past 19 years. He developed the first home monitoring program for cystic fibrosis patients, and has been the principal investigator on NIH sponsored research studies of home monitoring for lung transplant recipients since 1992. He and Dr. Speedie, the co-principal investigator, recently completed the TOP TeleHomeCare program focused on delivery of skilled nursing care to elderly, homebound patients using videoconferencing, Internet access, and physiological monitoring. Dr. Speedie also directs the Fairview - University of Minnesota Telemedicine Network that has provided telemedicine services for the last seven years to clinics throughout rural Minnesota and is now developing telemedicine links between tertiary care centers, rural hospitals, and rural health clinics. He has extensive experience in evaluating computer-based health care innovations. Dr. S. Potthoff, the evaluator for the TeleHomeCare project, will lead the VALUE evaluation.. She has extensive experience in health programs evaluation. M. Ideker, the rural site director, has been Director of Patient Services at TCH in Wadena MN since 1986. She is an experienced nurse with an advanced degree in Public Administration and is the Project Co-Director for the Fairview-University of Minnesota Telemedicine Network. M. Struwe is the Home Care Director at VOA/ Minnesota. She will manage the VOA VALUE team. She has 27 years of nursing experience and program administration with expertise in implementing technically enhanced service delivery. Finally all of our clinical partner sites have been providing both AL and home health services to

patients for many years and are highly experienced in providing such services in their respective geographical areas.

Implementation and completion. Eligible subjects will be at least 65 years old living independently in the community, managing one or more chronic disease, will be able to physically manipulate the system controls, can read and understand instructions, and have a telephone. Of the approximately 800 eligible clients, a total of 100 subjects (50 at each site) will be recruited. They will be randomized into an intervention group (VALUE) and a control group (continuing with usual independent living arrangement) at each site. Written informed consent will be obtained from all subjects. VALUE nurses will evaluate each subject for monitoring needs. All subjects will complete a well-being (the SF-36) and telemedicine perception questionnaire (TMPQ). ^{13,14} The nurse will use the ADL/IADL components of OASIS (Outcome & Assessment Information Set) to assess functionality. Then the VALUE workstation will be installed and the subject trained in its use. All subjects will complete the TMPQ again after 8 weeks to see if perceptions change with use of the system. SF-36 and ADL/IADL ratings will be determined every 8 weeks. All subjects will complete a patient satisfaction survey (HCCSI) after the first 3 months and quarterly thereafter to track changes as they become more familiar with the system and as its novelty lessens. ¹⁵ Subjects will remain in the study from a minimum 6 to 12 months, depending on recruitment date, or until the end of the program, they move on to a higher level of care, move from the area, or die. The project nurse at each site will be the contact person for all subject questions; technical questions will be forwarded to the co-principal investigators if they cannot be addressed locally. All visits will be carried out by the project nurse. A nurse case manager will be responsible for scheduling training home visits, virtual visits, and follow-up care.

Schedule. The project will require 36 months over 4 overlapping phases.. Phase 1 (6 months): Planning, purchase equipment, install central stations at the 2 partner sites, establish link with the University of Minnesota center, develop training programs for health care providers and subjects, begin training clinical personnel, consult with system users (prospective subjects and health care providers), and conduct focus groups with community leaders and prospective subjects at both sites. Phase 2 (12 months): Develop and test the VALUE workstation, refine and integrate the central workstation technology and develop the project web-site and individualized client participant web pages with symptom and monitoring reporting capability, pilot test the system with 3 clients at each site. Train staff in system use and provide lesson plans for subject training. Integrate virtual visits into AL guidelines. All providers will keep a log documenting each interaction and noting both successful use and problems that occur. Share information with all project personnel via weekly project teleconferences. Modify and enhance the system as needed. Phase 3 (17 months): Recruit subjects, implement the full system, and initiate data follow-up. Phase 4 (5 months): Evaluation of study data, writing the study final report, and implementing the dissemination plan. A timeline is shown in the Appendix.

Privacy/security. All confidential client information will reside behind appropriate security protection - at least password protected and likely encrypted as well. All patient data residing in the clinical information system will be privacy protected both by the physical security of residing in limited access rooms and by password protection within the system itself. All systems, including Internet transmission of client information, will be HIPAA compliant. Dr. Speedie's

telemedicine project has already developed a highly secure, HIPAA compliant website for patient information that will be adapted for use in this project. ¹⁶

Sustainability. This project is being undertaken because of the active interest of the University and its partners in providing cost-effective access to quality alternatives to traditional AL services. In particular, the partners are in the heath delivery business; their interests focus on expanding their services and client base by bringing these services to a traditionally underserved population in both urban and rural settings. If we are able to demonstrate that the system can maintain or lower costs while maintaining or improving quality and patient satisfaction, then our partners pledge to adopt the system for continued use in their programs. A successful demonstration of a cost-effective high quality telemedicine alternative to AL will establish the justification for other providers throughout the country to begin such programs. The dissemination support from AARP will provide a broad spotlight to initiate and sustain similar efforts nationally. The 100 subjects in the VALUE program should be sufficient to demonstrate statistically significant improvements in outcome variables, thus demonstrating the feasibility and potential of the VALUE concept, and providing a model for such programs that can be easily replicated by health care and assisted living agencies nationally. VALUE hardware is off-theshelf, thus available to all interested organizations. The content and delivery of VALUE will also be available through project publications, demonstrations, and the VALUE website. Our experiences in similar situations (e.g home monitoring of lung transplant patients and the TeleHomeCare project) have confirmed the power of small, well designed demonstrations leading to new reimbursement policy and eventual broader application and adoption.

Long-term support for a VALUE-like program is more likely to occur now than just a few years ago. Reimbursement for telehomecare has recently become a reality in many local and state jurisdictions. In Minnesota, Medical Assistance reimburses at a normal rate and Medicare recognizes a virtual visit and will allow it in addition to a traditional visit. In other states, HMO's have adopted policies to reimburse for telehomecare services after seeing the benefits. Likewise, cost containment for Medicare patients will eventually have a positive effect on the financial viability of the VALUE approach. We believe this has resulted from successful telehomecare demonstrations and knowledgeable lobbying on the part of interested provider organizations. Successful demonstration programs and actively involved provider agencies will continue to be the driving forces behind change, including agency adoption and third party reimbursement. A positive outcome from a randomized clinical trial like VALUE will accelerate these policy changes.

Budget. Budget details appear in the Budget narrative section. We do not believe this study would be fundable by other agencies interested in telemedicine, such as OAT (Office for Advancement of Telehealth) or RUS (Rural Utilities Service). OAT grantees must focus exclusively on rural health. The RUS Telemedicine Program is also focused on rural sites, and will not provide funding for medical, educational, or administrative personnel. VALUE is more broadly based, incorporating the needs of both rural and urban subjects; and relies on personnel support available through TOP (and partner match) to make the program succeed. Other funding agencies such as NIH or NSF typically fund basic science studies, and are less likely to consider demonstration programs such as VALUE.